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DIRECT DIAL:

April 22, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Re: Citizen Petition to Refrain From and Suspend Proceeding With Rulemaking Under Docket Numbers 96P-0023 and 96P-0179, Reference Amounts for Candies, and to Evaluate the Criteria and Procedures Needed to be Followed In Any Effort to Revise Existing Reference Amounts

Dear Sir or Madam:

On behalf of Brach and Brock Confections, Hershey Foods Corporation, and Nestle USA, Inc., we are filing this petition concerning FDA's January 8, 1998 proposed rules regarding the establishment of new reference amounts for candies. 63 Fed. Reg. 1078. We have carefully evaluated this proceeding in light of the importance of reference amounts and serving sizes to the consumer's appreciation of the nutritional quality of food and in light of the undeniable care FDA employed in developing existing requirements regarding reference amounts and serving sizes. Since the closing of the comment period on the proposed rules, we have considered the history of the proceeding, analyzed the supporting data, reviewed the comments the agency has received, and studied the programmatic and policy implications presented. We believe the proposed rules not only are flawed but also will have fundamental implications on future efforts to revise established reference amount categories.

I. Summary of Action Requested and Basis for Petition

Pursuant to 21 C.F.R. § 10.30, we request the agency to refrain from and suspend proceeding with its current activity concerning the proposed rules, evaluate the procedures employed and the decisions reached in the process of issuing the proposals

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and, before proceeding further with regard to establishing reference amounts for candies, determine whether more science-based policies, procedures, and data collection and evaluation criteria than are provided in 21 C.F.R. § 101.12 can be developed to guide efforts to revise existing reference amounts. The agency's rulemaking process to establish new reference amounts for candy products presents unresolved issues regarding the adequacy of the data and analysis underlying FDA's proposal and raises policy and procedural issues that could set precedents beyond the candy category concerning the appropriate basis for amending existing reference amounts. These issues and precedents deserve broader public comment and more precise agency consideration.

The agency's rulemaking was initiated by industry petitions seeking limited and targeted adjustments in the existing reference amounts. Both petitions relied on identical data from two in-home consumption surveys the protocols for which FDA not only reviewed but also agreed with. The results of the surveys included the quantity of data points contemplated by the guidance FDA had developed and relied upon in setting the original reference amounts following enactment of NLEA. Nevertheless, FDA proceeded to dismiss these data as well as other submitted data in favor of data from USDA's 1994 and 1995 Continuing Survey of Food Intakes by Individuals.

In fact, relying on the USDA data in general, FDA, instead of simply dealing with the petitions as filed, took the rather extraordinary and presumptuous approach of crafting a broad proposal to shift numerous candy products from the existing 40 gram reference amounts for "all other" candy to reference amounts of 15 and 30 grams. In so doing, FDA divided the universe of products into eight categories and concluded from the USDA data that they "resolved into three groupings" around the proposed reference amounts of 15, 30 and 40 grams. Upon review of the proposal and the USDA data, however, it is evident that, with respect to the proposed reference amounts, FDA is encompassing within single reference amounts an array of diverse products with a wide range of intakes and is doing so on the basis of a nominal number of data points per product.

As a consequence of this approach, the proposal has generated controversy and attracted considerable adverse comment from the candy industry. Of more fundamental importance, the proposal raises the general question of what data are

required and what criteria should be applied in amending existing reference amounts. Presumably, after five years of industry and public reliance on the original reference amounts, changes should be made on the basis of persuasive data and in accordance with well-understood criteria. These issues affect the entire food industry and the broad public interest in sound implementation of NLEA and, thus, should be clarified by FDA and subjected to additional public comment before FDA proceeds further with this rulemaking.

To be clear, this petition is not requesting reinstatement of the industry petitions giving rise to FDA's proposed rules. Rather, petitioners are of the view that the candy reference amount proceeding, as it has evolved, has identified the clear need for FDA to establish data requirements evaluative criteria, and procedures that industry can rely upon and that the agency will adhere to in any effort to revise existing reference amounts for any food.

II. Background to Action Requested

A. Nutrition Labeling and the NLEA

The Nutrition Labeling and Education Act of 1990 amended the Federal Food, Drug, and Cosmetic Act in an effort to achieve a comprehensive program for communicating meaningful, reliable and clear nutrition information to consumers. The framers of the amendments recognized that a key to any such effort was the establishment of realistic and consistent serving sizes. As a result, the NLEA directed FDA to establish standards for deriving serving sizes and defined "serving size" as that amount "customarily consumed which is expressed in a common household measure that is appropriate to the food . . . ." Section 403(q). At the core of the statutory requirement is the fundamental notion that consumers will benefit from a system that ensures uniformity and accuracy in serving sizes. The desired result, of course, is to facilitate the ability of consumers to make meaningful comparisons among similar products.

To implement the serving size requirements of the amendments, the agency embarked on a thoughtful and thorough course of rulemaking in which it established reference amounts customarily consumed per eating occasion for well over 100 food

product categories and corresponding procedures for determining serving sizes (for use on product labels) based on the reference amounts. To ensure consistent decisionmaking, the agency developed and followed detailed and careful procedures in establishing the reference amounts currently found in 21 C.F.R. § 101.12. *See*, for example, reference 6 ("Background Documentation for Determining the Reference Amounts Customarily Consumed Per Eating Occasion for Candies") to the agency's January 8, 1998 proposal. Moreover, as part of the initial process for developing reference amounts and serving sizes, FDA established an interagency committee that developed general principles and rules as part of a government-wide effort. The committee reviewed data on the amount of food customarily consumed per eating occasion and other information on serving sizes and developed product categories and reference amounts. In sum, the agency's efforts leading up to the adoption of the existing reference amounts for foods were as thoughtful, thorough and data-based as possible.

B. History of the Candy/Reference Amount Proceeding

On October 27, 1995, Andes Candies, Inc. submitted a citizen petition requesting that the reference amount customarily consumed for its mint wafer products be lowered from 40 grams to 15 grams. A second petition involving candy products was submitted by the Chocolate Manufacturers Association ("CMA") and the National Confectioners Association ("NCA") on May 30, 1996. The petition requested that FDA establish a new reference amount for candies (other than hard candies or baking candies) weighing 20 grams or less per piece. The petition requested that the reference amount for such candies be lowered from 40 grams to 25 grams. The proposal was supported by two surveys commissioned jointly by the two trade associations. Representatives of the associations discussed the protocols for the surveys with FDA officials prior to conducting the research. Based on the results of the surveys, the associations chose to petition for a reference amount that slightly overstated (25 grams vs. 20 grams) the observed consumption pattern.

C. The January 8, 1998 Proposal

In response to the petitions, FDA proposed to amend the nutrition labeling regulations by

- modifying the product category "Sugars and Sweets, Hard candies, others" to include "after-dinner mints, caramels, fondants (*e.g.*, plain mints, candy corn) and liquid and powdered candies" and assigning these products a reference amount of 15 grams;

- adding a new product category under "Sugars and Sweets," identified as "Chocolate-covered fondants (*e.g.*, chocolate-covered creams, chocolate-covered mints), taffy and plain toffee" with a reference amount of 30 grams; and

- clarifying what kinds of candies belong to the "All other candies" product category by expanding the name of the product category to include specific examples (*e.g.*, "candy bars, chocolate candies, fudge, licorice, gumdrops, nut or raisin candies") and to retain for such products the reference amount of "40" grams.

The agency's proposal went beyond the scope of the actions requested in the petitions and came as a surprise to the candy industry and the petitioners. Moreover, the approach FDA followed in creating new reference amount categories differed from that suggested by CMA and NCA: in essence, the agency relied only on data concerning very broad product codes and categories and refused to consider specific product data as requested by the petitioners. The agency also raised questions about the methodologies used by CMA and NCA in conducting and interpreting their consumption surveys. The agency differed with the trade associations and Andes concerning what the data showed with regard to customarily consumed amounts and concluded that the collected data suggested that some candies may be consumed in amounts "significantly" different from the 40 gram figure for "all other candies" currently reflected in the regulations.

Instead of simply rejecting the petitions or referring them back to the petitioners, the agency assembled its own data package by relying on information from the U.S. Department of Agriculture's 1994 and 1995 Continuing Survey of Food Intakes by Individuals. In applying these data FDA first identified the candy codes from the 1994-95 USDA survey database that, in the agency's view, reflected the candies specified in the petitions. The agency concluded that eight categories were represented. Next, the

agency calculated the consumption amounts for each of the eight groups. Then, based on "general principles" for developing reference amounts, the agency concluded that the data revealed that the eight groups "resolved into three groupings" reflecting the distinct reference amounts of 15 grams, 30 grams and 40 grams.

D. Comments on the Proposed Rule

In spite of the small universe of products and manufacturers affected by the proposed changes, several substantive comments have been submitted on the proposal. The comments reflect real concerns about a number of issues, including:

- the failure of the information and data in the record to statistically support the conclusion that the proposed 15 gram and 30 gram reference amounts are more characteristically representative of consumption patterns than the current 40 gram figure;

- the potential for the proposed 30 gram reference amount to create inconsistencies within product lines that have approximately the same ingredient composition but that would, due to differing serving sizes, have differing nutritional values (*e.g.*, the ambiguity that exists with chocolate-covered boxed candy, which includes items that would fall within the 40 gram category if sold as bars or in packages other than "boxes" but would fall within the 30 gram category if sold as boxed chocolates).

Comments also contend that, with regard to the new 30 gram category, the rule would result in a precedent for agency-based initiatives neither accompanied by a clearly established need nor supported by a convincing database upon which consensus can be reached.

Simply put, the comments point to the need for careful rethinking of the effects of the proposed rule and the propriety of the 15 and 30 gram reference amounts in particular.

III. Statement of Grounds for the Action Requested

The agency's January 8, 1998 proposed rulemaking reflects the challenges presented by attempting to develop appropriate new reference amounts for food categories as diverse and changing as candies. In our view, the revisions FDA has proposed to the existing required values are not clearly supported by convincing data and information. They must be. Otherwise, the ultimate goals of enhancing the consumer's ability to make a valuable nutritional comparison and avoiding consumer confusion cannot be assured. Simply put, real questions exist regarding the propriety of FDA's decision to employ USDA's broad food codes to candy corn and chocolate-covered fondants in light of the fact that available data reveal that the affected candy categories include an array of diverse products with a very wide range of consumption.

FDA's proposal to establish the product category of chocolate-covered "fondant" is also troublesome in light of the limited sample sizes for many of the candies comprising the category. These small numbers alone are not fatal to the development of a reasonable estimate but, according to the procedures FDA has employed in the past, the uncertainty that accompanies their reliability calls for a companion assessment whether the survey values relied upon were consistent with one another. *See supra*, Ref. 6, to January 8, 1998 proposal. Consumption data show that the values were, in fact, not consistent but encompassed a broad range of amounts from 7.6 grams to as many as 210 grams. For example, the 1994-95 USDA survey data concerning "eating occasions" for chocolate-covered fondants reveal that out of a possible 109 eating occasions:

- in 49 an amount over 30 grams was consumed;
- in 37 an amount over 40 grams was consumed; and
- in 14 amounts ranging from 66 grams to 110 grams were consumed.

Similar results are seen with inclusion of the 1996 USDA data.

Since the USDA data reveal that many products falling within the "chocolate-covered fondant" category are consumed in larger quantities than 30 grams, a

question arises whether the existing record clearly supports a compelling reason to change from the current 40 gram figure. Again: revisions to the agency's carefully derived existing values must be clearly supported.

Moreover, the implications of the agency's proposal extend well beyond candies and affect future agency and industry efforts to revise existing reference amounts for comparable food categories, including cookies, breads, snacks, and desserts -- to mention just a few. To this end, the controversy over the appropriate criteria for the collection and interpretation of data with regard to revising the reference amounts for candies is not only more significant than FDA appreciated but also signals the need for thoughtful consideration concerning the contours of such criteria in general.

The proceeding raises yet another issue of common concern: the procedures to be followed in any effort to revise an established reference amount. Viewed objectively, the procedures followed by Andes and by CMA and NCA seemed well designed to produce rational rulemaking. The petitions were consistent with the requirements of 21 C.F.R. § 101.12(h) governing the submission of petitions; were narrow in scope; and reflected the policy decision not to understate consumption. The clear gist of the petitions was to ensure that the NLEA-based emphasis on customary levels of consumption be accommodated in a way that if the petitions were to err, they would do so on the side of the consumer. Moreover, in the case of CMA and NCA, the submission of the petition was preceded by consultation with the agency regarding substantiation of the desired change. In fact, the petition was based on data from surveys the design of which was accepted by FDA.

In spite of this rather rigorous pre-submission preparation, the proposal offered by the agency barely resembled that offered in either the Andes or associations' petition. The agency rejected, in large part, the submitted data, expanded the scope of the proposed petition and went well beyond the proposed categories. The comments reveal clear differences of opinion regarding the propriety of the agency's tentative decisionmaking. Without question, further opportunity for dialog and discussion between petitioners and the agency before the agency issued its proposal would have been a desirable, helpful preliminary step prior to proposal. In fact, such an interim step

represents a far more reasonable response to the industry petitions than proposing the dramatically different alternative now pending.

Be the case candies or any other common food, revisions to FDA's carefully derived existing reference values should be the product of clear criteria governing data collection and evaluation and procedures designed to enhance decisionmaking if the ultimate goals of avoiding consumer confusion and enhancing the consumer's ability to make valuable nutritional comparisons are to be assured on a consistent basis. The January 8 proposal and the agency's procedures leading up to the proposal fall short of these goals and have the potential to impact broadly on future efforts to revise reference amounts for product categories other than candies.

IV. Requested Action

We request that all current agency activity concerning the proposed rules be suspended until the agency has evaluated the procedures employed and the decisions reached in the process of issuing the proposed rules. Before proceeding further with regard to establishing reference amounts for candies, we request the agency consider whether science-based policies, procedures and data collection and evaluation criteria can be developed beyond the limited guidance provided in Section 101.12(h) that would apply across the board to efforts to revise existing reference amounts. We specifically request that the agency focus and seek comment on the following issues of concern to the food industry as a whole:

- What are the appropriate data collection requirements and data evaluation criteria upon which to base a revision and what is the appropriate burden of proof necessary to supplant reference amounts originally deemed satisfactory for consumers and which consumers have relied upon in making nutritional decisions?

- Is it possible to establish uniform procedures regarding the design and scope of studies necessary to support changes to existing reference amounts and, if so, should such procedures contemplate greater opportunity for industry and agency consultation and

cooperation in study design and data evaluation prior to any formally proposed agency action to revise an existing reference amount?

Sound public policy grounds support this request. So does the administrative record of the proceeding. Moreover, no public health or public interest consideration outweighs the request. Examination of how best to proceed on the important, precedential issues raised by the proposed rules is the first step to ensuring sound, science-based and consistent agency decisionmaking in this and future proceedings.

V. Environmental Impact

The requested action is categorically exempt from the requirement for an environmental assessment, pursuant to 21 C.F.R. § 25.30(k), because it involves the perpetuation of an existing labeling requirement and will not result in any change in levels of use, or intended uses, of food products.

VI. Economic Impact

Information concerning economic impact will be submitted upon request.

VII. Certification

The undersigned certifies that, to his best knowledge and belief, this petition includes all information and views on which the petition relies, and it includes the representative data and information known to the petitioners which are unfavorable to the petition.

Sincerely,

Fred H. Degnan